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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,940	03/01/2002	Sean T. O'Mara	920070.417	6662

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EXAMINER	
LEWIS, AARON J	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/086,940	O'MARA, SEAN T.	
	Examiner	Art Unit	
	AARON J. LEWIS	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-71* is/are rejected.

7)☒ Claim(s) *72* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/02.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3,5-7,12,15-18,33-37,39-46,51,59,61-71 are rejected under 35 U.S.C. 102(b) as being anticipated by Flam ('386).

As to claim 1, Flam ('386) discloses an apparatus comprising: an intubation tube placement device (10); and an anti-perforation device (21,22) coupled to said intubation tube placement device.

As to claim 2, Flam discloses a semi-rigid structure (12 and col.6, lines 24-25) having a cross section smaller than a cross section of an intubation tube (24).

As to claim 3, Flam discloses said semi-rigid structure (12) to have a cross section of a cylindrical shaped rod.

As to claim 5, the anti-perforation device of Flam being a fiberoptic device includes a light source (col.7, line 49).

As to claim 6, Flam discloses an external light source (col.7, line 49). A source of power (ac wall outlet or battery) is a necessary part of any light source for a fiberoptic device.

As to claim 7, Flam (col.7, lines 50-59) discloses said intubation tube placement device forms a hollow tube (i.e. note insufflation and suction lumen that extends entire

length of device); said anti-perforation device having a trailing portion (e.g. adjacent handle #13) and an exploratory portion (e.g. adjacent tip of device #21) and a channel (col.7, lines 50-59) between the trailing portion and the exploratory portion of said anti-perforation device; and the trailing portion coupled to said intubation tube placement device such that the channel aligns with the hollow tube.

As to claim 12, Flam discloses the anti-perforation device (12) to have a trailing portion (e.g. adjacent handle #13) and an exploratory portion (e.g. adjacent tip of device #21), the exploratory portion being formed from a malleable material (col.6, line 24).

As to claims 15-17, Flam (figs.2,3,5,7) discloses an intubation tube (24) secured to the intubation tube placement device (12), the intubation tube placement device being internal to the intubation tube and a retaining device comprising a rubber stopper (23) having a hole through which the intubation tube placement device (12) extends, the retaining device being in contact with said intubation tube.

As to claim 18, Flam as discussed above with respect to claims 15-17, discloses an intubation placement device guide (24A) having a hole through which the intubation placement device (12) extends, the intubation placement device guide also being illustrated in figs. 3 and 8 as being integral with said intubation tube (24).

As to claim 33, Flam discloses an intubation tube placement device (12,13); and an intubation tube (24) secured to said intubation tube placement device.

As to claim 34, Flam (fig.2) illustrates the intubation tube placement device to comprise a semi-rigid structure (col.6, line 24) having a smaller cross section than the cross section of the intubation tube (24).

As to claims 35-37, the semi-rigid structure of Flam is shaped as a cylindrical shaped rod and is fully appropriate (i.e. shape and size are easily compatible with a variety of patients of differing sizes and ages) for use in a human adult, human child or infant as well as in a non-human adult, non-human child animal or neonate infant animal.

As to claim 39, the semi-rigid structure of Flam (col.6, line 24) is also disclosed as a malleable material.

As to claims 40 and 41, Flam (fig.2) discloses said intubation tube placement device (12) internal to the intubation tube (24); and a retaining device (23 rubber stopper) inserted into said intubation tube, the rubber stopper having a hole through which said intubation placement device (12) extends.

As to claim 42, Flam (figs.3 and 8) discloses an intubation placement device guide (24A) integral with said intubation tube (24); said intubation placement device guide having a hole, said intubation tube placement device internal to the intubation placement device guide hole.

As to claims 43 and 44, Flam discloses an anti-perforation device (22 bronchoscope) having a light source (col.7, lines 48-50).

As to claims 45 and 46, Flam (col.7, lines 50-59) discloses said intubation tube placement device forms a hollow tube (i.e. note insufflation and suction lumen that extends entire length of device); said anti-perforation device having a trailing portion (e.g. adjacent handle #13) and an exploratory portion (e.g. adjacent tip of device #21) and a channel (col.7, lines 50-59) between the trailing portion and the exploratory

portion of said anti-perforation device; and the trailing portion coupled to said intubation tube placement device such that the channel aligns with the hollow tube.

As to claim 51, Flam as discussed above with respect to claims 45 and 46 also teaches the exploratory portion of the anti-perforation device being formed from a malleable material (col.6, line 24).

As to claim 59, Flam discloses a tapered tip on the intubation tube (24) as illustrated in figs.5 and 6.

As to claim 61, Flam as discussed above also discloses a handle (13) affixed to the intubation tube placement device.

As to claim 62, Flam discloses an intubation tube (24) secured to said intubation tube placement device.

As to claims 63 and 64, Flam (fig.2) discloses said intubation tube placement device (12) internal to the intubation tube (24); and a retaining device (23 rubber stopper) inserted into said intubation tube, the rubber stopper having a hole through which said intubation placement device (12) extends.

As to claim 65, Flam (figs.3 and 8) discloses an intubation placement device guide (24A) integral with said intubation tube (24); said intubation placement device guide having a hole, said intubation tube placement device internal to the intubation placement device guide hole.

As to claim 66, Flam (figs.5 and 6) illustrates a method of intubation comprising inserting an intubation tube placement device (12,21), secured to an intubation tube (24), into a patient's oral cavity; forcing the intubation tube placement device through

the patient's vocal cords (e.g. fig.5); and axially sliding the intubation tube along the intubation tube placement device such that the intubation tube follows the intubation tube placement device through the patient's vocal cords (fig.6).

As to claim 67, the intubation tube placement device of Flam includes a light source (col.7, lines 48-50).

As to claims 68 and 69, Flam discloses suctioning materials from a vicinity of the patient's vocal cords via a suction tube formed by the intubation tube placement device (col.7, lines 51-59).

As to claim 70, Flam (col.7, lines 50-59) discloses said intubation tube placement device forms a hollow tube (i.e. note insufflation and suction lumen that extends entire length of device); said anti-perforation device having a trailing portion (e.g. adjacent handle #13) and an exploratory portion (e.g. adjacent tip of device #21) and a channel (col.7, lines 50-59) between the trailing portion and the exploratory portion of said anti-perforation device; and the trailing portion coupled to said intubation tube placement device such that the channel aligns with the hollow tube.

As to claim 71, Flam (figs.5 and 6) discloses manual manipulation of the intubation tube placement device (col.8, lines 16-21,44-50) into a patient's trachea. The application of axial pressure during manual manipulation of the intubation tube placement device of Flam is required in order to advance the device from a patient's mouth and into the trachea.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 4,8-11,13,38,47-50,52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flam ('386) in view of Barthel et al. ('698).

The difference between Flam and claim 4 is the semi-rigid structure being formed from a medical grade polymeric material.

Barthel et al., in an intubation apparatus, teach a semi-rigid structure (30,31) being formed from a medical grade polymeric material (col.4, lines 36-38 and line 59) for the purpose of avoiding scraping of accumulated biological material from the wall of the endotracheal tube and alleviates the problem of scraped up material collecting on the distal end of the viewing assembly and obscuring the endoscopic view (col.3, lines 13-17).

It would have been obvious to make the semi-rigid structure of Flam from medical grade polymeric material because it would have avoided scraping of accumulated biological material from the wall of the endotracheal tube and alleviated the problem of scraped up material collecting on the distal end of the viewing assembly and obscuring the endoscopic view as taught by Barthel et al..

As to claims 8 and 9, Barthel et el. teach the exploratory portion of the anti perforation device having a spheroid shape (32) which extends beyond the diameter of the intubation placement device (col.4, lines 54-55).

As to claim 10, Barthel et al. as discussed above with respect to claims 8 and 9, teach an exploratory portion having spheroid shape (32), the spheroid shape also being readable upon an angled shape.

As to claim 11, Barthel et al. as discussed above with respect to claims 8 and 9, teach an exploratory portion having spheroid shape (32), the spheroid shape also being readable upon a blunted shape that extends beyond the diameter of the intubation placement device.

As to claim 13, at least a portion of the outer surface of the spheroid shape (32) of the exploratory portion of the anti-perforation device of Barthel et al. forms an oblique angle with respect to the long axis of the intubation tube placement device.

As to claim 38, Flam as modified by Barthel et al. as discussed above with respect to claim 4 teach the semi-rigid structure being formed from a medical grade polymeric material.

As to claims 47 and 48, Barthel et al. teach the exploratory portion of the anti perforation device having a spheroid shape (32) which extends beyond the diameter of the intubation placement device (col.4, lines 54-55).

As to claim 49, Barthel et al. as discussed above with respect to claims 47 and 48, teach an exploratory portion having spheroid shape (32), the spheroid shape also being readable upon an angled shape.

As to claim 50, Barthel et al. as discussed above with respect to claims 8 and 9, teach an exploratory portion having spheroid shape (32), the spheroid shape also being

readable upon a blunted shape that extends beyond the diameter of the intubation placement device.

As to claim 52, at least a portion of the outer surface of the spheroid shape (32) of the exploratory portion of the anti-perforation device of Barthel et al. forms an oblique angle with respect to the long axis of the intubation tube placement device.

5. Claims 14,19-21,23,27-32,53,54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flam ('386) in view of Slanetz, Jr. ('091).

The difference between Flam and claim 14 is the anti-perforation device being proximate to a tactile accentuator flap.

Slanetz, Jr. teaches an anti-perforation device (12) proximate to a tactile accentuator flap (25) for the purpose of preventing the rupture of a duct by signaling a control unit of an area of greatest pressure being exerted on the tactile accentuator flap (col.2, lines 43-47 and lines 62-65).

It would have been obvious to modify the anti-perforation device of Flam to include a tactile accentuator flap proximate to the anti-perforation device because it would have provided a means for preventing the rupture of a duct by signaling a control unit of an area of greatest pressure being exerted on the tactile accentuator flap situated proximate an anti-perforation device as taught by Slanetz, Jr..

As to claim 19, Flam as modified by Slanetz, Jr. as discussed above with respect to claim 14, teaches an intubation tube placement device (#21,22 of Flam) having at least one tactile accentuator flap (#25 of Slanetz, Jr.) coupled to said intubation tube placement device.

As to claim 20, Flam discloses a semi-rigid structure (col.6, line 24) having a cross section smaller than the cross section of an intubation tube (24).

As to claim 21, Flam discloses the semi-rigid structure to comprise a cylindrically shaped rod (12).

As to claim 23, the outer surface of the tactile accentuator flap (25) of Slanetz, Jr. (fig.1) forms a non-zero angle with the long axis of the intubation tube placement device (12).

As to claims 27 and 28, Flam as modified by Slanetz, Jr. teaches said at least one tactile accentuator flap (#25 of Slanetz, Jr.) proximate to and coupled to an anti-perforation device (#12 of Slanetz, Jr..

As to claim 29, Flam discloses an intubation tube (24) secured to said intubation tube placement device (12).

As to claims 30 and 31, Flam (fig.2) discloses said intubation tube placement device (12) internal to said intubation tube (24); and a retaining device (23, rubber stopper) inserted into said intubation tube, the rubber stopper having a hole (figs.3 and 8), the intubation tube placement device (12) internal to the rubber stopper hole.

As to claim 32, Flam (figs.3 and 8) discloses an intubation placement guide (24A) integral with said intubation tube (24); said intubation placement guide having a hole, said intubation tube placement device (12) internal to the intubation placement guide hole.

As to claim 53, Flam as modified by Slanetz, Jr. as discussed above with respect to claim 14, teaches at least one tactile accentuator (#25 of Slanetz, Jr.) coupled to said intubation tube placement device.

As to claim 54, the outer surface of the tactile accentuator flap (25) of Slanetz, Jr. (fig.1) forms a non-zero angle with the long axis of the intubation tube placement device (12).

6. Claims 22,24-26,55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flam ('386) in view of Slanetz, Jr. ('091) as applied to claims 14,19-21,23,27-32,53,54, above, and further in view of Barthel et al. ('698).

The difference between Flam as modified by Slanetz, Jr. and claim 22 is the semi-rigid structure being made of medical grade polymeric material.

Barthel et al., in an intubation apparatus, teach a semi-rigid structure (30,31) being formed from a medical grade polymeric material (col.4, lines 36-38 and line 59) for the purpose of avoiding scraping of accumulated biological material from the wall of the endotracheal tube and alleviates the problem of scraped up material collecting on the distal end of the viewing assembly and obscuring the endoscopic view (col.3, lines 13-17).

It would have been obvious to further modify the semi-rigid structure of Flam to make the semi-rigid structure from medical grade polymeric material because it would have avoided scraping of accumulated biological material from the wall of the endotracheal tube and alleviated the problem of scraped up material collecting on the distal end of the viewing assembly and obscuring the endoscopic view as taught by Barthel et al..

As to claim 24, Flam as further modified by Barthel et al. as discussed above with respect to claim 22 teaches a semi-rigid structure having at least one tactile accentuator flap (#25 of Slanetz, Jr.) forming a non-zero angle with the long axis of the intubation tube placement device and being formed from a medical grade polymeric material.

As to claim 25, while Flam as further modified by Barthel et al. teach the semi-rigid structure to have a cylindrical facial profile, it would have been obvious to modify the shape of the facial profile of Flam to be of any desired shape including one having a 1mm by 1mm facial profile as an obvious matter of design choice with no new or unobvious results accruing. Inasmuch as applicant has not provided any criticality for the 1mm by 1mm facial profile, it is submitted that the cylindrical shape of the semi-rigid structure of Flam would have performed as well as one having a 1mm by 1mm facial profile.

As to claim 26, Flam discloses said semi-rigid structure being affixed to a ring-like structure (23) encompassing said intubation tube placement device (12).

As to claim 55, Flam as further modified by Barthel et al. as discussed above with respect to claim 22 teaches a semi-rigid structure having at least one tactile accentuator flap (#25 of Slanetz, Jr.) forming a non-zero angle with the long axis of the intubation tube placement device and being formed from a medical grade polymeric material.

As to claim 56, while Flam as further modified by Barthel et al. teach the semi-rigid structure to have a cylindrical facial profile, it would have been obvious to modify the shape of the facial profile of Flam to be of any desired shape including one having a 1mm by 1mm facial profile as an obvious matter of design choice with no new or

unobvious results accruing. Inasmuch as applicant has not provided any criticality for the 1mm by 1mm facial profile, it is submitted that the cylindrical shape of the semi-rigid structure of Flam would have performed as well as one having a 1mm by 1mm facial profile.

As to claim 57, Flam discloses said semi-rigid structure being affixed to a ring-like structure (23) encompassing said intubation tube placement device (12).

7. Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Flam ('386) in view of Davis ('478).

The difference between Flam and claim 58 is the apparatus being enclosed in sterile packaging.

Davis (col.9, lines 13-17 and lines 25-28) teaches enclosing an intubation device within sterile packaging prior to use in order to prevent contamination of a patient.

It would have been obvious to enclose the device of Flam within sterile packaging prior to use because it would have prevented patient contamination as taught by Davis.

8. Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Flam ('386) in view of Adair ('940).

The difference between Flam and claim 60 is a vented tip on the intubation tube.

Adair, in an intubation apparatus, teaches an intubation tube having a vented tip (i.e. Murphy eye) for the purpose of providing an alternate pathway for the flow of breathable gases in case the distal tip becomes blocked with mucous and/or debris.

It would have been obvious to modify the tip of the intubation tube of Flam to include a vent (i.e. Murphy eye) because it would have provided an alternate pathway for the

flow of breathable gases in case the distal tip becomes blocked with mucous and/or debris as taught by Adair.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Regarding claims 26 and 57, the phrase "ring-like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by hyphenated "-like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Allowable Subject Matter

11. Claim 72 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

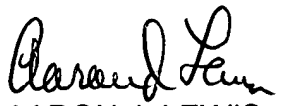
12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of the art is cited to show relevant intubation devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



AARON J. LEWIS
Primary Examiner
Art Unit 3743

Aaron J. Lewis
April 04, 2005